

REMARKS

This Response is being filed in connection with the Office Action mailed September 8, 2004. Claims 1 to 12 and 14 to 47 are pending. Claims 14 to 35 have been withdrawn from consideration as directed to a non-elected invention. Claims 1 to 12 and 36 to 47 are therefore under consideration.

Regarding the Amendments

The amendments to the claims are supported by the specification or were made to address informalities. In particular, the amendment to claims 1, 2, 36 and 37 to recite "migration-increasing or migration-decreasing" amount of galectin-3 was made in order to address an informality with the claim language. The amendment to claims 1, 2, 36 and 37 is also supported, for example, by originally filed claims 3, 4 and 8 to 13; at page 3, line 3, which discloses that migration may be stimulated or inhibited; and at page 9, lines 19-20, which discloses that "migration of cells can be modulated, that is stimulated, inhibited or directed." The amendment to claims 6 and 41 to recite that the recited galectin-3 comprises a "fragment of galectin-3," and that the recited galectin-3 binding antibody comprises a "binding fragment of galectin-3 binding antibody," respectively, was made in order to address an informality with the claim language. Thus, as the amendments to the claims are supported by the specification or were made to address informalities, no new matter has been added and entry thereof is respectfully requested.

I. REJECTIONS UNDER 35 U.S.C. §112

First Paragraph

The rejection of claims 8 to 13 and 43 to 47 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed. The rejection has been maintained based upon how to maintain a sufficient concentration of galectin-3 at the desired site in order to modulate cell migration. [Office Action mailed January 21, 2004, see pages 6C to 7, first paragraph]

The claims prior to and following entry of the amendments are adequately enabled. Nevertheless, as set forth above the claims have been amended for reasons unrelated to patentability and without acquiescing to the propriety of the rejection solely in order to further

prosecution of the subject application. The ground for rejection will be addressed as it may pertain to the amended claims.

Applicants first respectfully point out that cells are recruited towards galectin-3 injected into mouse air pouches *in vivo* (page 35, Example 8; and Figure 11). Thus, the data indicates that sufficient galectin-3 is maintained at the desired site. Second, if diffusion of galectin-3 were sufficient to cause cell migration away from the site, the number of cells present in the air pouch would have been less than the control (saline only). However, the data clearly indicate that the cell numbers increase in the air pouch relative to control. Because galectin-3 modulates cell migration *in vivo* towards the intended site, galectin-3 diffusion away from the intended site is therefore unlikely to be a significant issue. Consequently, even if there is some diffusion of galectin-3, given that the data disclosed in the specification indicate that cells migrate towards the intended site, any galectin-3 diffusion that may occur is unlikely to be sufficient to cause migration away from the intended site.

Third, even if galectin-3 diffuses, as it diffuses it is likely that galectin-3 becomes degraded. Thus, galectin-3 is unlikely to accumulate by diffusion at a sufficiently high concentration to modulate cell migration away from the intended site.

Finally, Applicants respectfully remind the Patent Office that the law does not require the dosage to be specified if it is known that one skilled in the art could obtain a dosage without undue experimentation. Here, determining dosages for modulating cell migration are well within the level of the skilled artisan, in view of the guidance in the specification and knowledge in the art (see, for example, page 10, lines 4-12; and page 19, lines 16-21).

In sum, in view of 1) the data indicating that galectin-3 modulates cell migration *in vivo*; 2) the absence of data indicating that galectin-3 diffusion causes cells to migrate away from the intended site; and 3) that accumulation of galectin-3 in sufficient amounts to cause migration away from the intended site is unlikely due to degradation, diffusion of galectin-3 is unlikely to cause migration away from the intended site. Consequently, claims 8 to 13 and 43 to 47 are adequately enabled and Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, for alleged lack of enablement be withdrawn.

Second Paragraph

The rejection of claims 1 to 12 and 36 to 47 under 35 U.S.C. §112, second paragraph, as allegedly indefinite is respectfully traversed. The rejection is due to the alleged use of circular claim language.

Claims 1 to 12 and 36 to 47 are clear and definite under 35 U.S.C. §112, second paragraph, prior to entry of the amendment. Nevertheless, as set forth above the claims have been amended for reasons unrelated to patentability and without acquiescing to the propriety of the rejection solely in order to further prosecution of the subject application.

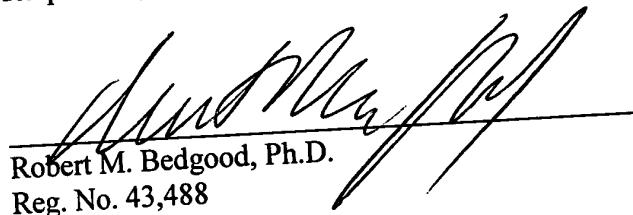
Amended claims 1, 2, 36 and 37 recite "a migration-increasing or migration-decreasing amount of galectin-3." Amended claims 6 and 41 recite that galectin-3 comprises a "fragment of galectin-3," and that the galectin-3 binding antibody comprises a "binding fragment of galectin-3 binding antibody," respectively. Thus, in view of the amendment, the grounds for rejection of claims 1 to 12 and 36 to 47 is moot. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 1 to 12 and 36 to 47 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065. Please charge any additional fees, or make any credits, to Deposit Account No. 03-3975.

Respectfully submitted,



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